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10/825,085	04/15/2004	Bernhard B. Sterling	OPTIS.107A	7177

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EXAMINER	
UNDERWOOD, JARREAS C	

ART UNIT	PAPER NUMBER
2877	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,085	STERLING ET AL.	
	Examiner	Art Unit	
	Jarreas C. Underwood	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *39-48* is/are allowed.

6)☒ Claim(s) *1-13,17-26,28,29,31-38 and 49* is/are rejected.

7)☒ Claim(s) *14-16,27 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *15 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because the lines in Figures 25, 30A-B, 31A-B, 34A-B, 35A-B are indistinguishable and not labeled. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: paragraph 0145 makes reference to chamber walls 202. Element 202 does not appear on any figure, and elements 202a, 202b, 202c and 202d designate the chamber walls.

Appropriate correction is required.

Claim Objections

3. Claim 33 is objected to because of the following informalities: The first sentence defines a method to determine the ratio of an analyte to the total volume of a sample (analyte over sum of analyte plus first substance plus second substance), which is inconsistent with the last step which calculates a ratio of the analyte to other components (analyte over sum of first substance plus second substance).

For purposes of examination the examiner assumes "ratio of the third quantity divided by the sum of the first quantity and the second quantity" to read, "ratio of the third quantity divided by the sum of the first quantity, the second quantity and the third quantity." Appropriate correction is required.

4. Claim 36 is objected to because of the following informalities: The word hemocrit is only indirectly defined by Figure 22. The dictionary definition of "hemocrit" indicates the word should be "hematocrit", which is incompatible with its use in claim 36. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. The term "hemocrit" in claim 36 is used by the claim to mean "everything in a volume of blood except plasma and glucose" (Figure 22), while the accepted meaning is that of the word hematocrit, "the proportion of blood that consists of red blood cells, expressed as a percentage by

volume." The term "hemocrit" is indefinite because the specification does not clearly redefine the term. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-49 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Methods that lack a tangible product, or conveyance of a result (i.e. gedankenexperiments) are inadmissible. The examiner suggests including an LCD display screen or similar device that produces a concrete result to a user.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Sterling et al (U.S. Patent 6,862,534).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Examiner draws attention to the Certificate of Correction to patent 6,862,534 filed on 1 March, 2005 amending the list of Inventors.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1; 9-12, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kajiwara, K; Fukushima, H; Kishikawa, H; Nishida, K; Hashiguchi, Y; Sakakida, M; Uchara, M; Shichiri, M; ("Spectroscopic Quantitative Analysis Of Blood Glucose By Fourier Transform Infrared Spectroscopy With An Attenuated Total Reflection Prism"; Medical Progress Through Technology 18, No. 3; 1992; pp 181-189) (Hereafter referred to as Kajiwara).

9. As to claim 1, Kajiwara discloses a method of determining an analyte concentration in a sample, the sample comprising the analyte and a substance, the method comprising: providing absorption data of the sample; providing reference absorption data of the substance; calculating a substance contribution of the absorption data; and subtracting the substance contribution from the absorption data of the sample, thereby providing corrected absorption data of the analyte substantially free of a contribution from the substance (Abstract and Materials and Method, pp 182-183).

10. As to claim 9, Kajiwara discloses everything claimed, as applied above, including calculating the substance contribution comprises providing reference substance absorption data; scaling the reference substance absorption data by multiplying the reference substance absorption data by a scaling factor; and subtracting the scaled reference substance absorption data from the absorption data, thereby providing the corrected absorption data (Abstract, and Materials and Method, pp 182).

11. As to claim 10, Kajiwara discloses everything claimed, as applied above, including the substance comprising water (Materials and Method; Glucose in aqueous solutions, pp 182).

12. As to claim 11, Kajiwara discloses everything claimed, as applied above, including that the substance interferes with determining the analyte concentration (Abstract).

13. As to claims 12 and 18, Kajiwara discloses everything claimed, as applied above, including the sample further comprising a second substance which interferes with determining the analyte concentration to a lesser extent than does the substance, the method further comprising calculating a second substance contribution of the absorption data and subtracting the second substance contribution from the absorption data, thereby providing twice-corrected absorption data substantially free of contributions from the substance and from the second substance (Abstract, and Discussion; pp 188, right column, paragraph 1).

14. As to claim 17, Kajiwara discloses everything claimed, as applied above, including scaling the reference substance absorption data utilizing at least two wavelength ranges (Results; pp 183).

15. Claims 1, 9, 13, 18-26, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Malin et al (U.S. Patent 6,115,673).

16. As to claim 1, Malin discloses a method of determining an analyte concentration in a sample, the sample comprising the analyte and a substance, the method comprising: providing absorption data of the sample; providing reference absorption data of the substance; calculating a substance contribution of the absorption data; and subtracting the substance contribution from the absorption data of the sample, thereby providing corrected absorption data of the analyte substantially free of a contribution from the substance (column 4, line 54 – column 5, line 41).

17. As to claim 9, Malin discloses everything claimed, as applied above, including calculating the substance contribution comprises providing reference substance absorption data; scaling the reference substance absorption data by multiplying the reference substance absorption data by a scaling factor; and subtracting the scaled reference substance absorption data from the absorption data, thereby providing the corrected absorption data (column 10, lines 36-46).

18. As to claim 13, Malin discloses the reference substance absorption data is corrected for temperature-dependent effects (column 5, lines 20-24).

19. As to claim 18, Malin discloses everything claimed, as applied above, including the sample comprising a second substance, and the method further comprising

subtracting a second contribution corresponding to the second substance from the corrected absorption data, thereby providing twice-corrected absorption data substantially free of contributions from the substance and from the second substance (column 5, lines 15-41).

20. As to claim 19, Malin discloses everything claimed, as applied above, including providing second reference absorption data corresponding to the second substance; scaling the second reference absorption data by multiplying the second reference absorption data by a second scaling factor', and subtracting the scaled second reference absorption data from the corrected absorption data, thereby providing the twice-corrected absorption data (column 5, lines 15-41, and column 10, lines 36-46).

21. As to claims 20-22, Malin discloses everything claimed, as applied above, including second substance comprising a whole blood protein, components of a boundary layer between water and a whole blood protein, urea or lactate (column 4, line 54 – column 5, line 14).

22. As to claims 23-24, Malin discloses everything claimed, as applied above, including fitting the twice-corrected absorption data with analyte spectral data, thereby yielding a measurement of the analyte concentration in the sample, or with reference analyte spectral data. (column 5, lines 15-41, and column 10, lines 36-46).

23. As to claims 25-26, Malin discloses a method of providing measurements of constituents in a sample using infrared (1R) spectroscopy, the method comprising: providing absorption data of the sample; and correcting the absorption data for a non-analyte contribution to the absorption data. In addition wherein providing absorption

data comprises: placing the sample in a cuvette having a shape; passing IR radiation through a filter having a finite width; irradiating the cuvette with the IR radiation; and detecting a fraction of the IR radiation transmitted through the cuvette and the sample (column 14, lines 17-40, and column 5, lines 15-41).

24. As to claims 31-32, Malin discloses everything claimed, as applied above, including the sample comprising blood or plasma (column 4, line 54 – column 5, line 14).

Claims 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Steuer et al (U.S. Patent Application Publication 2002/0038079).

25. As to claim 33, Steuer discloses a method of using infrared (IR) spectroscopy to determine a ratio of an analyte volume to the total volume of a sample (paragraph 0048) comprising the analyte, a first substance, and a second substance (paragraph 0059), the method comprising:

providing absorption data from the sample for a first set of wavelengths in a wavelength region where a first-substance absorption dominates; calculating a first quantity equal to the product of a first-substance volume concentration and a path length of the sample (equation 1a, paragraphs 0077, 0107, 0115 and 0116);

providing absorption data from the sample for a second set of wavelengths in a wavelength region where the first-substance absorption and a second-substance absorption dominate; calculating a second quantity equal to the product of a second-substance volume concentration and the path length of the sample (equation 1a, paragraphs 0077, 0107, 0115 and 0116);

providing absorption data from the sample for a third set of wavelengths in a wavelength region where the first-substance absorption, the second-substance absorption, and an analyte absorption dominate; calculating a third quantity equal to the product of an analyte volume concentration and the path length of the sample (equation 1a, paragraphs 0077, 0115 and 0116);

and calculating a ratio of the third quantity divided by the sum of the first quantity and the second quantity (equation 9 and the definition of hematocrit).

26. As to claims 34-38, Steuer teaches samples comprising glucose, water, hemoglobin and red blood cells (paragraphs 0014 and 0048).

27. Claim 49 is rejected under 35 U.S.C. 102(b) as being anticipated by Jöbsis (U.S. Patent 4,805,623).

Jöbsis teaches a method of determining an optical pathlength of a sample (column 4, lines 31-35) comprising water and a whole blood protein (column 7, lines 44-49), the method comprising measuring an optical absorption of the sample at an isosbestic wavelength and calculating the optical pathlength of the sample from the optical absorption (column 4, lines 35-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajiwara in view of Steuer (U.S. Patent Application Publication 2002/0038079).

28. As to claim 2, Kajiwara discloses everything claimed, as applied above, with the exception of providing transmittance data of the sample and determining the absorption data from the transmittance data. However, to do so is well known as taught by Steuer. Steuer discloses a method of obtaining transmission data transmissively (paragraph 0051) and using the Beer-Lambert Law to obtain absorption data (paragraphs 0052-0054 and http://en.wikipedia.org/wiki/Beer-Lambert_law). It would have been obvious to one having ordinary skill in the art at the time of invention to obtain data transmissively and use transmission data to obtain absorption data, in order to non-invasively determine biologic constituent values, such as hematocrit.

29. As to claim 3, Kajiwara discloses everything claimed, as applied above, with the exception of transmitting at least a portion of an infrared signal through the sample, the infrared signal comprising a plurality of wavelengths; and measuring the portion of the infrared signal transmitted through the sample as a function of wavelength. However, to do so is well known as taught by Steuer. Steuer discloses a method of transmitting at

least a portion of an infrared signal through the sample (paragraph 0051), the infrared signal comprising a plurality of wavelengths (Figure 2); and measuring the portion of the infrared signal transmitted through the sample as a function of wavelength (Figure 2). It would have been obvious to one having ordinary skill in the art at the time of invention to utilize multiple wavelengths in transmission data acquisition in order to include wavelengths with acceptable combinations of sufficient penetration depth and sufficient sensitivity in ascertaining glucose concentrations.

30. As to claim 4, Kajiwara discloses everything claimed, as applied above, with the exception of placing the sample in a cuvette. However, to do so is well known as taught by Steuer. Steuer teaches placing the sample in a cuvette (paragraph 0049). It would have been obvious to one having ordinary skill in the art at the time of invention to place the sample in a cuvette in order to perform in vitro measurements.

31. As to claims 5 and 6, Kajiwara teaches samples comprising blood (Abstract) and the analyte comprising glucose (Abstract), and the selected transmittance wavelength range comprises wavelengths at which the transmittance data is dominated by water transmittance (Results, pp 183).

32. As to claims 7 and 8, Kajiwara discloses everything claimed, as applied above, with the exception of the sample comprising plasma, the analyte comprising glucose. However to do so is well known as taught by Steuer. Steuer teaches samples comprising blood and the analyte comprising glucose (paragraph 0014). It would have been obvious to one having ordinary skill in the art at the time of invention to use a

sample comprising plasma and an analyte comprising glucose, in order to the values of critical life support functions (e.g. hematocrit).

33. As to claim 9, Kajiwara discloses everything claimed, as applied above, including calculating the substance contribution comprises providing reference substance absorption data; scaling the reference substance absorption data by multiplying the reference substance absorption data by a scaling factor; and subtracting the scaled reference substance absorption data from the absorption data, thereby providing the corrected absorption data (Abstract, and Materials and Method, pp 182).

34. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malin in view of Burns (U.S. Patent 5,876,121).

Malin discloses everything claimed, as applied above, with the exception of the non-analyte contribution being dependant on the temperature of the sample. However, to do so is well known as taught by Burns. Burns discloses a method of determining the non-analyte contribution that is dependant on the temperature of the sample (column 6, lines 15-41). It would have been obvious to one having ordinary skill in the art at the time of invention to determine the non-analyte contribution that is dependent on the temperature of the sample, in order to determine calibration coefficients.

35. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malin in view of Thomas (U.S. Patent 6,441,388).

Malin discloses everything claimed, as applied above, with the exception of the non-analyte contribution being dependant on the temperature of the filter. However, to do so is well known as taught by Burns. Burns discloses a method of determining the

non-analyte contribution that is dependant on the temperature of the filter (column 9, lines 31-42). It would have been obvious to one having ordinary skill in the art at the time of invention to determine the non-analyte contribution that is dependent on the temperature of the filter, in order to provide representation of intra-instrument spectral effects.

Allowable Subject Matter

36. Claims 14-16, 27, 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record, taken alone or in combination, fails to disclose or render obvious corrections to the reference substance absorption data for wavelength-dependant nonlinearities generated by scattering or fringing from the sample element (claims 14-16), a non-analyte contribution from a finite width of the filter (claim 27), a non-analyte contribution from the shape of the cuvette (claim 30),

37. Claims 39-48 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record, taken alone or in combination, fails to disclose or render obvious the use of cuvette distortion matrix elements, calculating residuals between the exact and calculated optical densities, and determining the analyte concentration error by calculating the analyte concentration consistent with the difference between the residuals at the analyte reference wavelength and the measurement wavelength.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Clift (U.S. Patent 5,452,716); Essenpreis et al (U.S. Patent 5,710,630); Hansen (U.S. Patent 6,980,285); Jeng et al (U.S. Patent 6,067,463); Lepper (U.S. Patent 6,278,522); Nygaard et al (U.S. Patent 5,252,829).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jarreas C. Underwood whose telephone number is (575) 272-1536. The examiner can normally be reached on Monday-Friday 0800-1630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley can be reached on (571) 272-2059. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jarreas Underwood

Patent Examiner
Art Unit 2877
4/28/2006

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PRIMARY EXAMINER